California Health and Human Services Agency
Committee for the Protection of Human Subjects (CPHS)

CPHS staff only
Date Received:
Date to Review:
Due Date:
Final Approval:

CONTINUING PERIODIC REVIEW FORM — DATA-ONLY

PROJECT NO.:
PROJECT TITLE:

PI Name (please print):
PI's Phone #:
E-mail:
Address:
Other Contact Person Name (if applicable):
Phone #:
E-mail:
Other Contact Title:

Please respond to the following issues and questions:

1. Status of project:
   - ☐ **Continuing:** Please attach any findings to date and include a copy of all publications.
   - ☐ **Completed:** Please attach any findings to date and include a copy of all publications.
   - ☐ **Withdrawn:** Please provide in the cover letter an explanation of why the project is being withdrawn.
   - ☐ **HIPAA waiver or alteration of authorization requested:**
     Please include in the cover letter a statement as to whether there have been any changes in data security practices or other factors relevant to the continuing of the waiver.
2. List the formal names of any California Health and Human Services Agency (CHHSA) databases, such as the Cancer Registry, or specimens, such as blood spots, to be used in this project.

Department	**Name of Database(s)/Specimen(s)**
Dept. of Public Health	
Dept. of Health Care Services	
Office of Statewide Health Planning and Development	
Dept. of Mental Health	
Dept. of Developmental Services	
Dept. of Social Services	
*	
*	

3. Check the box(es) which indicates the nature of each CHHSA department's involvement – e.g., Funding (pass through or source of funding), Principal Investigator (PI), research staff involved (staff), or supplying human subjects (note that **only** subjects for which the State has direct responsibility, e.g., mental hospital patients should be included.). *Specify any other CHHSA departments involved.

Department	**Funding**	**PI**	**Staff**	**Subjects**
DPH	☐	☐	☐	☐
DHCS	☐	☐	☐	☐
OSHPD	☐	☐	☐	☐
DMH	☐	☐	☐	☐
DDS	☐	☐	☐	☐
DSS	☐	☐	☐	☐
*	☐	☐	☐	☐

* Specify other department(s) involved.

4. Indicate the amount of funding project receives from each source listed below.
Federal $ _____ State $ _____ Foundation $ _____ Other $ _____
Total $ _____

5. Has the analysis of data ended?

☐**Yes** ☐ **No**

6. Have any complaints, verbal or written, been received from data sources?

☐**Yes** ☐ **No**

(***If "Yes,"*** attach a copy and description of details.)

7. Have there been any adverse events?

☐**Yes** ☐ **No**

(***If "Yes,"*** attach a ***detailed*** explanation.)

8. Have there been any breeches of data security?

☐**Yes** ☐ **No**

(***If "Yes,"*** attach a *detailed* explanation.)

9. Have there been any difficulties or unanticipated problems experienced during the research?

☐**Yes** ☐ **No**

(***If "Yes,"*** attach a *detailed* explanation.)

10. Are you requesting any changes to your approved protocol, including use of additional years of data?

☐**Yes** ☐ **No**

(If "Yes", please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Please attach copies of old protocol with tracked changes and clean copies of new protocol with original signatures from Principal Investigator (P)I and Responsible Official (RO).)

11. Are you proposing any new documents or changes to other project documents (e.g., consent forms, survey instruments, questionnaires, translations, etc.)?

☐**Yes** ☐ **No**

(***If "Yes,"*** please specify and justify revisions and address whether revisions change subjects' risk level in the box below. Attach old materials with tracked changes and clean copies of new materials and ensure protocol reflects changes, as appropriate.)

:

12. Are you requesting a change in PI.or RO?

☐**Yes** ☐ **No**

(***If "Yes",*** please specify the previous PI or RO and the new PI or RO in the box below. If a new PI is being added, address conflict of interest questions, including description of financial or other relationships that could be perceived as affecting objective research and the interpretation and publication of findings. Submit new PI's curriculum vitae. See Instructions for Researchers, Appendix I, #12 for financial relationship examples.)

13. Date data collection began: _____

Number of proposed data records: _____

A. Total number of data records analyzed since project began: _____

B. Number of data records currently in analysis: _____

C. Number of data records analyzed in past year : _____

D. Number of data records deleted in past year: _____

E. Number of data records expected to analyze in coming year: _____

F. Expected total number of data records in project: _____

G. Expected completion date of project: _____

14. HIPAA - include any changes in data security practices or other factors that may be relevant to the waiver for HIPAA waiver of authorization, if applicable?

☐**Yes** ☐ **No** ☐ **NA**

(***If "Yes',*** explain in the box below)

15. Project Chronology - provide a dated sequence of significant events in the project's history, including all changes reviewed by CPHS in the box below.

16. Protocol Summary - provide a short description of the basic elements of the study as currently conducted in the box below.

17. Interim Findings - provide a summary statement of interim findings and other relevant information in the box below.

18. Literature Review – provide a summary of relevant scientific literature in the box below.

19. Attach any reports or publications related to this research.

Signature of P.I.: _____ **Date:** _____ **Project #:** _____

Name of PI (Please print or type): _____

CPHS Use Only

STAFF: Project eligible for Expedited Review due to:
☐ **Completed** or ☐ **Withdrawn**
☐ CPHS determined minimal risk
☐ All human intervention-related research has permanently ended
☐ No subjects enrolled & no added risks have been identified

☐ Yes ☐ No Revisions
☐ Yes ☐ No **HIPAA** approval or renewal required

Circle Reviewers:
Dickey Lowe Dinis Galbraith Harris Kirkish Mihordin Murphy Ruiz Snipes Ward Staff

REVIEWER:
☐ Yes ☐ No N/A ☐ Have adverse events (AE) been appropriately addressed by researcher and, if any AE, these AEs do not increase risk for subjects?
☐ Yes ☐ No N/A ☐ Is the currently approved informed consent forms still accurate & complete?
☐ Yes ☐ No N/A ☐ Is currently approved waiver or alteration of informed consent still justified?
☐ Yes ☐ No N/A ☐ Do interim findings justify continuation of the research?
☐ Yes ☐ No N/A ☐ Is recent literature adequately reviewed & support continued research?

If revisions:
☐ Yes ☐ No These revisions **are** minor
☐ Yes ☐ No These revisions **do not** increase risk to subjects
☐ Yes ☐ No. These revisions are **approved**
If No, is project referred to Full Committee? ☐ Yes ☐ No
Explain:
☐ Approved for **Common Rule** ☐ **Common Rule** deferred, pending minor revisions (Comments)
☐ Approved for one year ☐ Approved for less than one year, specify;_____

HIPAA:
☐ Approved HIPAA waiver ☐ Does not affect HIPAA (if applicable)
☐ HIPPA waiver deferred pending revisions

Translations:
☐ Approved translations

Completed or Withdrawn Project
☐ Yes ☐ No Is the plan for data destruction or return appropriate?
☐ Yes ☐ No Has PI provided sufficient information re: publications/reports?
☐ Yes ☐ No Are the reasons for withdrawal appropriate?
☐ Approved ☐ Not approved, explain:

Comments:

If revisions required: ☐ Member must confirm revisions ☐ Staff may confirm revisions
☐ CPHS staff approves revisions (initial and date):

CPHS Member or Staff Signature _____ **Date**_____

Please fax/scan the signed form to: CPHS Administrator Phone: 916-326-3660 Fax: 916-322-2512